DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 4 2005

Ms. Jolyn Tenllado
Regulatory Affairs Specialist
BioMérieux, Inc.
595 Anglum Road
Hazelwood, MO 63042-2320

Re: k043237
Trade/Device Name: VITEK® Gram Negative Moxifloxacin (concentrations of 2, 4, 8 µg/ml with calling range of ≤0.5 - ≥8 µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices
Regulatory Class: Class II
Product Code: LON
Dated: November 18, 2004
Received: November 22, 2004

Dear Ms. Tenllado:

This letter corrects our substantially equivalent letter of December 23, 2004, regarding the concentrations for the VITEK® Gram Negative Moxifloxacin (2 – 8 µg/ml) which was changed VITEK® Gram Negative Moxifloxacin (concentrations of 2, 4, 8 µg/ml with calling range of ≤0.5 - ≥8 µg/ml) to better reflect the intended use of the device.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k043237

Device Name: VITEK® Gram Negative Moxifloxacin (concentrations of 2,4,8 μg/ml with calling range of ≤ 0.5 – ≥ 8 μg/ml)

Indications For Use:

The VITEK® Gram Negative Susceptibility Test is intended to be used with the VITEK® System for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae*, and *S. pneumoniae*. VITEK® Gram Negative Moxifloxacin is designed for antimicrobial susceptibility testing of *Klebsiella pneumoniae, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca,* and *Proteus mirabilis*. VITEK Gram Negative Moxifloxacin is for qualitative testing only. It is intended for use with the VITEK System as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k043237